Zurich December 17, 2018

Dr. Daniela Marino
CEO
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Quality Assurance Specialist 80-100% Zurich-Schlieren

Job Description:
Object: Quality Assurance
Reporting/supervisor: CEO
Location: Zurich-Schlieren, Weinbergstrasse 35- Wagistrasse 27-
Start: February 2019
Contract: permanent
Language: English and German (French, Spanish or Italian is a plus)

Background:
CUTISS AG, a biotech company spin-off of the University of Zurich (UZH), focuses on the development of personalized bioengineered skin graft products for the treatment of skin defects. Its lead product denovoSkin™ has successfully completed Phase I in pediatric patients. Clinical Phase II studies are underway in Europe and Switzerland.

The qualified candidate is a highly motivated, interactive individual that possesses the ability to work individually and collectively. The successful candidate will demonstrate clear and professional verbal, written communication and reporting.

Description of Responsibilities:
Execute work in the major areas of:

- Quality Operations
    - Support implementation and maintenance of CUTISS' GMP Quality Management System (QMS).
    - Key activities include:
        - Writing and reviewing QMS documentation (standard operating procedures and related documentation).
        - Archiving of documentation
        - Supporting the Quality training programme and promoting quality awareness
        - Support internal and external audit acting as SME (Subject Matter Expert) and as part of the audit core team.
        - Handling of deviations and support in change management process

- GMP Operations and Manufacturing support:
    - Quality review and approval of validation documentation
    - Quality review and approval of manufacturing documentation
    - Review of manufacturing batch production records

- Research & Development Support:
    - Quality review and approval of Product and Process development documentation, including Study protocols and Study reports

- Quality compliance support:
    - Provide guidance and support in the area of Quality documentation (writing and reviewing SOPs and other documents related to quality management)
    - Support or Supervise the GMP Tech-transfer from Wyss institute to CUTISS (documentation and processes)

Degree/Education/Certification Requirements:
- Minimum requirements Bachelor or Master of Sciences with more than 2 years in GMP, in Quality assurance department

Required Skills and Experience:
- Must have work permit in Switzerland
- Excellent knowledge of GMP operations, ideally in manufacturing of biologics.
- Project management experience
- Demonstrate interpersonal, oral and written communication, and organizational skills
- Attention to detail with excellent organizational and record keeping
- Excellent interpersonal skills
- Fluent in English both oral and written

Desired Skills and Experience:
- Demonstrate ability to work independently
- Self-reliant in determining priorities
- Goal oriented
- Accurate
- Quality auditing expertise
- Good organizational and communication skills
- Good understanding of pharmaceutical industry trends and practices.
- Good working knowledge of EU and U.S GMP regulations, as well as pharmaceutical industry quality systems.
- Good computer skills e.g. Microsoft Office

Work Environment:
Laboratory/office environment.

We offer:

- High pace start-up environment
- flexible working hours in arrangement with the head of department
- competitive benefit package
- a young and dynamic team
- 5 weeks holidays